REMARKS

Claims 6, 9, 10, 12-15, 29, 31, 32 and 34-37 are pending and under examination. New claims 51 and 52 have been added. Support for these claims is found at, *inter alia*, page 5, lines 30 and 31 of the specification. Upon entry of this Amendment, claims 6, 9, 10, 12-15, 29, 31, 32, 34-37, 51 and 52 will be pending and under examination.

In view of the arguments set forth below, applicants maintain that the Examiner's rejection made in the March 10, 2006 Final Office Action has been overcome, and respectfully request that the Examiner reconsider and withdraw same.

The Claimed Invention

This invention provides methods of treating thrombosis, and decreasing plasma fibrinogen. These methods comprise administering an anti-TNF antibody or antigen-binding fragment thereof to a subject diagnosed as suffering from thrombosis.

This invention is based on applicants' *surprising discovery* that inhibiting the biological activity of TNFα reduces fibrinogen levels in a subject. Since fibrinogen plays an integral role in forming thrombi, this invention has considerable use for treating thrombosis in subjects diagnosed as suffering from thrombosis.

Rejection Under 35 U.S.C. §112, First Paragraph - Written Description

The Examiner rejected claims 6, 9, 10, 12-15, 29, 31, 32 and 34-37 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleged that neither the specification nor the claims, as filed, provide support for limiting treatment to subjects "diagnosed" as suffering from thrombosis. The Examiner further alleged that neither the specification nor the claims, as filed, provide support for the treatment of thrombosis, nor for the method of decreasing the level of plasma fibrinogen in a subject diagnosed with thrombosis.

In response to the Examiner's rejection, applicants respectfully traverse. Applicants point out that the subject specification provides support both for treating thrombosis and decreasing fibrinogen levels in a subject diagnosed with thrombosis.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

First, applicants note that the specification describes the notion of treating "thrombosis" in sufficient detail. For example, page 5, lines 34-35 of the subject specification indicates that the invention is directed to a method of

treating a "thrombotic disorder" in an individual. Furthermore, page 6, lines 2-9 of the specification indicates that a thrombotic disorder is a condition (such as deep vein thrombosis) where thrombosis is a pathogenic component. The specification also discloses, on page 6, lines 19-20, that the present invention can be used to treat "thrombosis". Thus, based on the subject disclosure, those skilled in the art would recognize that applicants were in possession of a method of treating "thrombosis" in an individual.

Second, those skilled in the art would recognize that the claimed methods would necessarily be used on individuals *diagnosed* as suffering from thrombosis. It would *not* be reasonable for those skilled in the art to conclude that the claimed methods would be used on individuals not diagnosed as suffering from thrombosis. In support of this position, applicants note M.P.E.P. §2163(I)(B), which states that "[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, *implicit, or inherent disclosure.*" (emphasis added). Thus, the specification need not explicitly state that the subject treated in the claimed methods be diagnosed with a particular disorder. The fact that treatment of thrombosis is clearly stated in the application constitutes an *inherent statement*, i.e. disclosure, that the subject being treated be diagnosed with that disorder. To conclude otherwise exhausts credulity.

Therefore, those skilled in the art can conclude, from the subject disclosure, that applicants were in possession of methods of treating thrombosis and decreasing plasma

fibrinogen in an individual diagnosed as suffering from thrombosis.

Finally, applicants note the addition of new claims 51 and 52 drawn to the instant methods wherein the thrombosis is deep vein thrombosis. The Examiner has concluded that treating deep vein thrombosis is clearly disclosed in the subject application, and applicants maintain that these claims satisfy the written description requirement.

In view of the above remarks, applicants maintain that claims 6, 9, 10, 12-15, 29, 31, 32, 34-37, 51 and 52 satisfy the written description requirements of 35 U.S.C. §112, first paragraph.

Summary

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
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